

REMARKS

Claims 1 to 15 were elected in response to the Restriction Requirement, and claims 16 to 24 stand withdrawn as being unelected. Claims 1 to 15 stand rejected under 35 USC §103(a) as being unpatentable over Fleischhacker (U.S. Patent No. 4,596,559) in view of Stephenson (U.S. Patent No. 4,526,172). The Specification is amended in Paragraph [0009] to provide express support for the amendment to claim 1, that the pinching member is translated between its open and closed positions; support is found in Figures 1 and 4 (as originally filed) when compared. The Specification is also amended at Paragraphs [0052] and [0053] to provide express support for the limitations of claims 5 and 6 as originally filed, to use consistent terminology.

Claim 1 is amended hereby to include the limitation that the pinch member is “translatable” between an open position and a closed position. Claims 2 and 8 are amended hereby to provide that the clamp assembly is operable by the same hand that also holds the insertion sheath (or sheath body). Support is found in Paragraph [0043] as originally filed, now Paragraph [0040.2], and in Paragraphs [0047], [0058], [0063] and [0067] as originally filed, while the advantage of this limitation is set forth in Paragraphs [0063] and [0064] wherein it is described that the physician’s other hand is free to insert the catheter into the sheath when the clamping members unclamp the sheath.

The Office Action set forth an objection under 35 USC §132(a) on the basis that the Preliminary Amendment filed November 16, 2006 added new matter to the application. However, regarding “open and closed” positions, this finds support in Paragraph [0007] line 6 and Paragraph [0008] line 6 as originally filed, and elsewhere, and therefore its entry into Paragraph [0009] is not new matter. Regarding “first and second pinch legs”, this finds support in Paragraph [0009] as originally filed, and elsewhere, and therefore its entry into Paragraph [0032] is not new matter. Regarding new Paragraphs [0040.1], this paragraph finds support in Paragraph [0044] as originally filed. Regarding new Paragraph [0040.2], this paragraph finds support in Paragraph [0043] as originally filed. The entry of new Paragraphs [0040.1], [0040.2] and [0048.1] is only a relocation of original Paragraphs [0042], [0043] and [0044] as originally filed, resulting in a more sensible flow of the Detailed Description, all as explained in the Remarks submitted in the Preliminary Amendment. Therefore, no new matter was entered and the objection is respectfully traversed.

Reference Fleischhacker discloses a disposable catheter introducer set with a break-away handle and splittable sheath. The sheath has two halves separated by a pair of opposed

splits and the two halves conclude in respective tabs at the proximal end. The handle comprises a pair of handle members (joined together at weakened portions) each comprising a pair of clamping elements (lower clamping portions 22 and upper clamping portions 29) which clamp therebetween the tabs of the sheath halves therebetween; the handle serves to initiate and facilitate the tearing apart of the two sheath halves, as well as to facilitate insertion of an introducer tool into the proximal end of the sheath.

The Office Action holds that element 22 releasably closes the sheath to prevent fluid flow through the sheath, and is movable to an open position allowing fluid flow therethrough. However, as is clearly shown in Figure 2, the sheath passageway is never closed by the elements 22, each of which is a lower clamping half of a respective one of the pair of clamping members, and is not closed by any other element disclosed in the reference. Therefore, the characterization of the reference Fleischhacker is respectfully traversed.

Reference Stephenson discloses a unitary, one-piece multipurpose plastic clamp adapted for a wide variety of uses. The clamp includes a pair of pivotally interconnected pincer portions and a pair of pivotally interconnected handle portions, with the pincer portions further respectively pivotally connected to the handle portions. Movement of finger grips defined by the handle portions toward each other creates a clamping force between the respective clamping surfaces of the pincer portions. Locking structures are also provided to hold the pincer portions in the clamping position.

The Office Action sets forth that it is obvious to combine the clamping device of Stephenson to the introducer sheath of Fleischhacker “to modify the catheter sheath... to provide the catheter sheath with a multipurpose pinch clamp for providing a disengageable [sic] locking structure to a tube.” However, there is no disclosure nor suggestion in either reference to so combine, especially since Fleischhacker does not disclose clamping its sheath.

Regarding claim 1 as amended, the clamping device of such a combination would not clamp closed the sheath by being translated, but would operate by pivoting of the handles toward each other as taught in Stephenson.

With respect to claims 2 and 8 as amended, there is no disclosure nor suggestion in the combined references that the combination even if made would allow the pinch member to be operable with the same hand that holds the sheath.

Furthermore, with respect to claims 3 to 12 and 13 to 15, there is no disclosure nor suggestion in either reference for a pinch member to “extend from the handle” especially since

the sheath's handle structure would be expected to actually obstruct the clamping closed of the sheath passageway by the clamping device of Stephenson.

Regarding claim 6, there is no disclosure in the references of a second tab and second recess, wherein the second tab engages the second recess. While Stephenson discloses a first tab and first recess at 52,54,56, elements 40 which appear also to be a tab and recess are taught in the reference at column 5, lines 5 to 13 to be clamping surfaces to clamp therebetween a flexible tube, not to engage each other.

With regard to claims 9 to 12 and claim 13 and its dependent claims 14 and 15, the combination even if made, does not meet the limitation of the pinch member extending through a slot of a catheter sheath clamp body.

Therefore, for the reasons above stated, the rejection of all of claims 1 to 15 is respectfully traversed.

No new matter has been added by these amendments, and allowance of all elected claims is respectfully requested.

Respectfully submitted,

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